## REMARKS

Claims 2-3, 8-12, 15, 26, 35-36, 38-45, 47-48, 56-58, 61, 71, 85, 100, 108, 112, 138 and 141 were previously canceled without disclaimer or prejudice. Claims 1, 4-7, 13, 14, 16-25, 27-34, 37, 46, 49-55, 59, 60, 62-70, 72-84, 86-99, 101-107, 109-111, 113-137, 139, 140, 142 and 143 remain before the Examiner for reconsideration.

In the Office Action dated May 24, 2004, the Examiner rejected claims 17-25, 27, 32-33, 62-70, 72, 77-84, 86, 104-107, 139-140, 142 and 143 under 35 U.S.C. Section 103(a) "as being unpatentable over Kranys et al (US Pat# 4,006,736) et al in view of Bernstein et al (US pat# 5,611,344)." Specifically the Examiner asserted that:

> Kranys discloses an angiographic injector that includes an injector, a syringe a plunger and a movement mechanism (28). The injector and syringe have means cooperable for mounting. The movement mechanism is connected to the syringe. The movement mechanism is operable to move the syringe in a semi-circular (rotational) path. The fluid within the syringe is an ultrasound contrast agent. When the syringes are rotated it is considered inherent that any fluid contained therein will be agitated during the movement. The method steps are considered inherent for proper function of the device. For example, since a syringe, injector and movement mechanism are all disclosed it is inherent that they all must be provided. During use, once the syringes are rotated the claim language of 'activating the movement mechanism' will be met. Once the syringes have complete a turn it is inherent that the step of 'deactivating the movement mechanism' has been met. See figures 2 and 3.
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> Kranys meets the claim limitations as described above but fails to include an agitation element that (i) has a density different from that of the fluid contained in the syringe, (ii) is a solid, (iii) is a gas and (iv) is surrounded by a cover. However, Bernstein discloses a microencapsulated fluorinated gas for use as an imaging agent. See summary of invention.
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> At the time of the invention, it would have been obvious to incorporate the imaging agent of Bernstein into the invention of Kranys. Bernstein discloses that this imaging agent has enhanced echogenicity compared with other agents. The motivation for the incorporation would have been in order to enhance the overall procedure of Kranys by using a known enhanced agent.

Applicants respectfully traverse the Examiner's rejection.

Kranys discloses an angiographic injector having a head portion which employs a rotating turret arrangement for housing two syringe cartridges at the same time. When one of the syringes of Kranys is in operative alignment with the piston drive, the other syringe is maintained in a state of readiness. When the first syringe is empty or has less contrast media than required in an ensuing injection procedure, the second, filled syringe is exchanged for the first syringe by turning the turret 180° by hand. Kranys thus improves upon the previously bothersome and time-consuming process of exchanging an empty syringe cartridge with a filled one that was necessary in the use of injectors available prior to Kranys angiographic injector.

Contrary to the Examiner's assertion, Kranys does not disclose that the fluid within the syringe is an ultrasound contrast agent. Indeed, only angiographic contrast agents are discussed in Kranys. Moreover, there is absolutely no disclosure or suggestion in Kranys of rotation of the turret thereof in a manner to effect agitation of any type of fluid.

Furthermore, it is unlikely that manual rotation of the turret of Kranys 180° to switch the syringe of Kranys in operative connection with the drive mechanism thereof would effect appreciable agitation of any fluid including, for example, an angiographic contrast agent. As set forth on page 1, lines 17 through 21 of the specification, manual movement of injectors, including the syringe, are not reproducible and sufficient homogenization is not assured. Even if an agitation element were included in the syringes of Kranys, it is doubtful that appreciable, if any, agitation of a fluid would occur upon manual rotation of the turret of Kranys. As set forth on page 3, lines 21 to 25 of the present specification, "the movements of the syringe must be such that the agitation element disposed within the syringe moves with respect thereto." Manual rotation of the turret of Kranys 180° to switch the syringe of Kranys in operative connection with the drive mechanism of Kranys, without other motion, is not likely to induce appreciable motion of any agitation element within the syringes of Kranys. However, as admitted by the Examiner, Kranys does not disclose or suggest the use of an agitation element in the

syringes thereof. Nonetheless, the Examiner asserts that Kranys can be combined with the disclosure of Bernstein to arrive at the present invention.

Initially, applicant respectfully asserts that Bernstein does not disclose or suggest an agitation element and thus cannot be combined with the disclosure of Kranys to arrive at the presently claimed invention. In that regard, Bernstein merely discloses that the echogenicity (that is, the reflection of ultrasonic waves) of synthetic polymer microparticles including air therein can be increased by the incorporation of a fluorinated gas in place of the air. The microparticles of Bernstein are part of the ultrasonic contrast agent and not an agitation element. Indeed, concentration gradients of such microparticles can result in an ultrasonic contrast agent as a result of the differences in density between such microparticles and the liquid carrier of the contrast agent. The agitation devices and methods of the present invention can be used in connection with contrast agents including the microparticles of Bernstein to reduce the effect of or eliminate such concentration gradients. Bernstein, on the other hand, does not disclose or suggest any agitation (either with or without an agitation element as claimed in the present invention) to create, maintain or restore homogeneity of a contrast agent including the microparticles of Bernstein or any other fluid.

Once again, an agitation element as claimed in the present invention is not disclosed or suggested in Bernstein. Moreover, even if Bernstein could be interpreted as disclosing an agitation element (which it cannot), one of ordinary skill in the art would not combine the disclosure of Kranys with that of Bernstein as there is absolutely no motivation in either reference or elsewhere in the prior art for such a combination. See, for example, *Ex parte* Chicago Rawhide Mfg. Co., 223 USPQ 351, 353 (P.O. Bd. Appl. 1984) ("The prior art must provide a motivation or reason for a worker in the art without the benefit of appellant's specification to make the necessary changes in the reference device."); Schenk v. Norton, 218 USPQ 698, 702 (Fed. Cir. 1983) ("Modification unwarranted by the disclosure of a reference is improper."); Ex Parte Acosta, 211 USPQ 636, 637 (P.O. Bd. Appls. 1980) (Examiner's combination of two references is improper where there is no basis in the record from which it can reasonably be inferred that one

skilled in the art would have been led or motivated to modify the primary reference in the manner proposed by the Examiner.) As discussed above, neither Kranys nor Bernstein even address the problem of creating, maintaining and/or restoring homogeneity of a contrast agent, via agitation or otherwise.

The Examiner also indicated that claims 28-31, 73-76, 87-90, 109-111, and 113-131 were objected to "as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims." Applicant respectfully asserts that in light of the above remarks, those claims are allowable as written.

The Examiner further indicated that claims 1, 4-7, 14, 16, 34, 37, 46, 49-60; 91-99, 101-103, 132-137 are allowed. Applicant appreciated the Examiner's indication of the allowance of those claims.

In view of the above amendments and remarks, the applicants respectfully requests that the Examiner withdraw the rejections of the claims, indicate the allowability of the claims and arrange for an official Notice of Allowance to be issued in due course.

Respectfully submitted,

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